K063283

EXHIBIT 2
510(k) Summary

NOV 17 2006

SEDECAL SA **Pelaya 9- Poligono Industrial Rio De Janeiro 28110 –Algete Madrid Spain** **Tel (34) 91-628 0544/91-628 1592** **Fax (34) 91-628 0574** **(Foreign Manufacturer)**	**GE Medical Systems, LLC** **3200 N. Grandview Blvd.** **Waukesha, WI 53188** **Phone: 262-544-3012** **Fax: 262-544-3863** **(Digital Panel Manufacturer** **Contact: Ms. Martha Kamrow**

September 18, 2006

1. Identification of the Device:
   Proprietary-Trade Name: Definium™ 5000 X-Ray System
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR and MQB
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: This notification is for a MODIFIED device. This device COMBINES two 510(k) cleared devices, the SEDECAL X PLUS LP PLUS Universal Radiographic Systems K062335 AND the GE Medical Systems Digital Radiographic Detector, K041922. This combination is functionally identical to a SEDECAL cleared device, Sedecal URS LP X-Ray Units with Digital Detector, K042876.

3. Indications for Use (intended use) The Definium™ 5000 X-Ray Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Device: The Definium 5000 Digital Radiographic Imaging System provides state of the art image quality, image manipulation, operator control, dose reporting and system maintenance. These features make this system easy to use and reliable while providing high quality radiographic images in a digital environment. The Definium 5000 System is designed to handle radiographic applications using the digital table. The system configuration includes an elevating or non-elevating table, a floor column stand with rotating U-arm, and GE's patented Digital Detector that captures radiographic images in digital form, as well as an X-ray generator/power unit. An Acquisition and Review Workstation for image post-processing, short-term storage, and quick in-room viewing of images is included as part of the system. Images may be transferred manually or automatically via a DICOM network for printing, long-term storage archive, and detailed review.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, The Definium™ 5000 X-Ray

Characteristic	Sedecal URS X-Ray Units with Digital Detector K042876	SEDECAL X PLUS LP PLUS Universal Radiographic Systems K062335	Definium™ 5000 (This Submission): Combines two cleared devices: K062335 AND K041922
Intended Use:	General purpose diagnostic X-ray unit	SAME	SAME
User Interface	Depends on Control Console option chosen. Mainly dedicated touch controls	Software Driven Touch Panel LCD, + IR remote control unit	Software Driven Touch Panel LCD, + remote control unit + remote console
Maximum output	Depends on model of generator chosen. Models available from 30 kW to 64 kW	SAME as original units.	64 Kw model only.
Image Acquisition	Digital: CANON CXDI-50G. K031447	Film	Digital: GE Tethered Portable Digital Radiographic Detector K041922
Digital Panel Size	Up to 14" x 17" active area	N/A	16" x 16" active area
Digital Resolution	160 x 160 microns pixel pitch, with approximately 6 million pixels	N/A	200 x 200 micron pixel pitch, approximately 4 million pixels.
Method of Control	Dedicated push button Controls	Software Driven Touch Panel LCD, +IR remote control unit	Software Driven Touch Panel LCD, +IR remote control unit and control room interface box.
Collimator	Manual R302/A	Manual R302/A and Automatic available	Automatic Collimator Heustis 150

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Sedecal that the Definium™ 5000 Radiographic System with Digital Detector is as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEDECAL SA
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

AUG 23 2013

Re: K063283
Trade/Device Name: Definium™ 5000 X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: October 30, 2006
Received: October 30, 2006

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of November 17, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062283

Device Name: Definium™ 5000 X-Ray System

Indications For Use:

Indications for Use: The Definium™ 5000 X-Ray System is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062283